

part D2
11. (Amended) An isolated peptide of 3 to about 100 amino acid residues in length which inhibits ristocetin induced aggregation of platelets, the isolated peptide being identified by:

selecting a library of test peptides, each test peptide being of 3 to about 100 amino acid residues in length;

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exposing the library of test peptides to a sample peptide consisting of an amino acid sequence as shown in SEQ ID NOs: 1-21, 23-75, or 77-81;

selecting test peptides from the library that bind to the sample peptide;

screening the selected test peptides for ability to inhibit ristocetin induced aggregation of platelets; and

identifying the screened test peptides that inhibit ristocetin induced aggregation of platelets.

REMARKS

Claims 7, 9 and 11 are pending in the subject application. Claim 7 has been canceled, and claims 9 and 11 have been amended. Therefore, the claims now under consideration are claims 9 and 11, as amended. Applicants respectfully request that the rejections of the claims be reconsidered and withdrawn in view of the above amendments and the following remarks.

35 U.S.C. §112, first paragraph, Rejections

On pages 2-3 of the office action, the Examiner rejects claims 7, 9 and 11 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description and as allegedly not enabled.

Applicants have reviewed the Examiner's rationale for this rejection, and point out that the claims have now been narrowed to: claim 9 - a peptide that binds to a specified amino acid sequence, SEQ ID NO: 1-21, 23-75, or 77-81; and claim 11 - a peptide that is identified by its ability to bind to a specified amino acid sequence, SEQ ID NO: 1-21, 23-75, or

77-81. These SEQ ID NOs represent the particular mimotopes disclosed in the specification.

In regard to claims 9 and 11, the identification of peptides that bind to these particular mimotopes is routine in the art, and the methodology is disclosed in the specification. See page 17, lines 13-14, "selecting from bacteriophage ... libraries", and page 27, line 5 to page 32, line 23, "Biopanning of Mab C-34 With Bacteriophage Display Libraries", particularly beginning on page 29 for the identification of peptides able to bind to the mimotope peptides. Amended claim 11 specifically claims the peptides by their method of identification using these routine and disclosed methods.

Furthermore, numerous references which disclose methodology for identifying anti-mimotope peptides that bind to particular mimotope peptides are cited in the specification. These references were known and available to the public prior to the filing date of the subject application, and include:

Balass, M. et al., Proc Natl Acad Sci USA 90:10638-10642 (November 1993);

Christian, R.B. et al., J Mol Biol 227:711-718 (1992);

Cwirla, S.E. et al., Proc Natl Acad Sci USA 87:6378-6382 (August 1990);

Hobart, M.J. et al., Proc R Soc London B 252:157-162 (1993);

LaRocca, D. et al., Hybridoma 11:191-201 (1992);

Scott, J.K., Trends in Biochem Sci 17:241-245 (1992);

Scott, J.K. and Smith, G.P., Science 249:386-390 (July 27, 1990); and

Smith, G.P. and Scott, J.K., Methods in Enzymology 217:228-257 (1993).

Copies of each of these references were provided to the Examiner with applicants' information disclosure statement.

In fact, the anti-mimotopes enumerated on pages 17-18 and 42-45 of the specification were identified in this manner.

In summary, applicants contend that the identification of peptides that bind to the specifically enumerated mimotope sequences is adequately described and enabled in view of the disclosure in the specification and the state of the art as of the filing date of the subject application. Furthermore, the claims, in addition to being limited in regard to the particular mimotope sequences, are also limited to those peptides that inhibit ristocetin induced aggregation of platelets. The identification of such peptides which have this desired functional property can be routinely done using, for example, the methodology disclosed in the specification at page 38, line 13 through page 40, line 20, "Aggregation Studies" and "Synthesized Peptide". When this readily identifiable functional limitation is combined with the structural description in relation to SEQ ID NOs: 1-21, 23-75 or 77-81, applicants contend that an enabling and adequate written description is provided for the invention as now claimed.

Lastly, the Examiner indicated that specific points relating to the enablement rejection as presented in the prior office action had not been addressed. The Examiner had previously indicated that "it is not routine in the art to screen large numbers of peptides to determine which would possess the structural and functional criteria of the claimed molecules based on the instant disclosure" absent "guidance, such as information regarding the amino acid features of the peptide in order to use the molecules in a manner reasonably commensurate with the scope of the claims." The issue for the subject application stems from the fact that all of the anti-mimotopes do not have a common structural feature in the sense of a common or consensus amino acid sequence. The structural definition of the claimed anti-mimotopes is presented in relation to the structurally defined amino acid sequence of the mimotopes to which the anti-mimotope peptides bind.

The Examiner in the prior office action also commented that the ability to bind to the mimotope alone seemed

insufficient to predict which peptides or other molecules would also inhibit ristocetin induced aggregation (referring to SEQ ID NOs: 94 and 104 and 106). Applicants point out that this point is why the claims as presented herein require the functional limitation of having the ability to inhibit ristocetin induced aggregation. And, contrary to the Examiner's comment that the "specification is silent with respect to ... the methods necessary to predict which peptides ... would fall within the scope of the claims", the specification discloses how to identify the peptides or antibodies and how to screen for the functional limitation (see above discussion). Since both of these readily identifiable limitations are present in the claims, applicants contend that the claims are adequately described and enabled.

Finally, the Examiner indicated that claim 7 lacked written description support due to the presence of new matter. Applicants point out that claim 7 has been canceled.

In view of the above amendments and remarks, applicants respectfully request that these §112 rejections be reconsidered and withdrawn. Applicants maintain that the claims as amended and added herein define patentable subject matter. A notice of allowance is therefore requested. Should any issues remain which can usefully be discussed by telephone, the Examiner is invited to contact applicants' undersigned attorney at the number provided.

Respectfully submitted,

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Date

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2-08-02	<u>Susan J. Braman</u>
Date	Susan J. Braman Attorney Reg. No.: 34,103



7. Canceled.

9. (Three Times Amended) An isolated peptide of 3 to about 100 amino acid residues in length capable of binding to a second peptide having an amino acid sequence as shown in [SEQ ID NO:174] SEQ ID NOs: 1-21, 23-75, or 77-81, wherein the isolated peptide inhibits ristocetin induced aggregation of platelets, and wherein the isolated peptide has a three dimensional structure complementary to the three dimensional structure of the second peptide.

11. (Amended) An isolated peptide of 3 to about 100 amino acid residues in length which inhibits ristocetin induced aggregation of platelets, the isolated peptide being identified by:

selecting a library of test peptides, each test peptide being of 3 to about 100 amino acid residues in length;

exposing the library of test peptides to a sample peptide consisting of an amino acid sequence as shown in [SEQ ID NO:174] SEQ ID NOs: 1-21, 23-75, or 77-81; [and]

selecting [a] test peptides from the library that bind[s] to the sample peptide;

screening the selected test peptides for ability to inhibit ristocetin induced aggregation of platelets; and

identifying the screened test peptides that inhibit [, wherein the selected test peptide is thereby identified as an isolated peptide which inhibits] ristocetin induced aggregation of platelets.